

**Application No. 09/785,831**  
**Amdt. dated February 23, 2004**  
**Reply to Office Action of October 23, 2003**

**REMARKS**

The Official Action of October 23, 2003 has been carefully considered. Applicants appreciate the Examiner's thorough review of the application. The changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, claims 21-27 and 103-124 have been canceled without prejudice and claims 125-167 have been added. Support for claim 125 can be found in original claims 21 and 24. Support for claims 126, 144 and 158 can be found in original claim 22. Support for claims 127, 134, 145, 151, 159 and 164 can be found in original claim 23. Support for claims 128, 135, 146, 152, 161 and 165 can be found in original claim 25. Support for claims 129-131, 138-142, 149, 150, 155, 156, 162, 166 and 167 can be found, for example, in FIG. 4 and in the specification on page 24, line 21 through page 25, line 19. Support for claims 132, 136, 147 and 153 can be found in original claim 26. Support for claims 133, 137, 148, 154 and 163 can be found in original claim 27. Support for claim 160 can be found in original claim 24. New claim 143 includes limitations from claims 21 and 105 and therefore can find support, for example, in original claim 21 and in FIG. 4 and in the specification on page 24, line 21 through page 25, line 19. New claim 157 includes limitations from claims 21 and 106 and therefore can also find support, for example, in original claim 21 and in FIG. 4 and in the specification on page 24, line 21 through page 25, line 19.

**Application No. 09/785,831**  
**Amdt. dated February 23, 2004**  
**Reply to Office Action of October 23, 2003**

Accordingly, claims 125-167 stand pending in this application and are believed to be in condition for allowance.

In the Official Action, the Examiner rejects claim 21-27 and 103-124 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,435,076 to Hjertman et al. in view of U.S. Patent No. 5,184,450 to Galy et al. or U.S. Patent No. 4,941,876 to Meyer et al. Applicants respectfully traverse this rejection and request reconsideration of claims 125-167 presented herein.

Specifically, Hjertman et al. in view of Galy et al. or Meyer et al. fail to teach or suggest the limitations of independent claims 125, 143 and 157. With respect to claim 125, the references fail to teach or suggest the claimed combination of steps, particularly wherein the front part of the sleeve is connected to the sealer after the step of sealing the front end opening with the sealer. With respect to claim 143, the references fail to teach or suggest the claimed combination of steps, particularly wherein the front end opening is sealed with the sealer in a sterilization zone and the front part of the sleeve is connected to the sealer outside the sterilization zone. These steps provide benefits in several exemplary embodiments of the invention. For example, a lypophilization step may be performed without the sleeve being present. Therefore, there is no danger of the sleeve inhibiting vapor passage from the chamber and no need to provide the sleeve with specific features to facilitate vapor passage. In still further examples, the sleeve can be connected to the sealer outside of the sterilization zone,

**Application No. 09/785,831**  
**Amdt. dated February 23, 2004**  
**Reply to Office Action of October 23, 2003**

thereby minimizing the parts that necessarily need to be sterilized and fed into the sterilization zone.

On the other hand, Hjertman et al. only appears to teach attaching the sleeve to the sealer prior to sealing the front end opening as discussed in the specification at column 7, lines 18-34. In fact, Hjertman et al. teaches away from connecting the sleeve to the sealer after the step of sealing the front end opening with the sealer. Hjertman et al. discusses the use of the sleeve to assist in sealing the front end opening with the sealer. For example, Hjertman et al. states that the "...sleeves 7 will guide the stoppers 11 into their correct places in the necks of the cartridges ..." (See column 7, lines 31-32). Galy et al. and Meyer et al. do not resolve these deficiencies in Hjertman et al.

With respect to claim 157, Hjertman et al. in view of Galy et al. or Meyer et al. similarly fail to teach or suggest the claimed method. In particular, the references fail to teach or suggest the claimed combination of steps, particularly wherein a second piston is inserted through a rear opening at the rear end of the barrel, and wherein the step of inserting the second piston is performed prior to the step of connecting the front part of the sleeve to the sealer. In fact, Hjertman et al. apparently teaches away from inserting the second piston prior to connecting the front part of the sleeve to the sealer. Hjertman et al. states that the front chambers are sealed prior to being removed from the freeze-drying apparatus. (column 7, lines 35-37). After removing the cartridges from the freeze-drying apparatus, the liquid component is filled into the cartridges through their rear ends which are subsequently closed

**Application No. 09/785,831**  
**Amdt. dated February 23, 2004**  
**Reply to Office Action of October 23, 2003**

by means of the pistons. (column 7, lines 37-40). Hjertman et al. therefore teaches away from inserting the second piston prior to the step of connecting the sleeve to the sealer since the sleeves are used to assist in sealing the cartridges in the freeze-drying apparatus and the second piston is subsequently inserted after removing the cartridge from the freeze-drying apparatus. Galy et al. and Meyer et al. do not resolve these deficiencies of Hjertman et al.

For the reasons set forth above, Applicants respectfully request allowance of claims 125, 143 and 157, as Hjertman et al. in view of Galy et al. or Meyer et al. fail to teach or suggest the combinations of steps recited in each claim. As claims 125, 143 and 157 are believed to be in condition for allowance, Applicants further request allowance of claims 126-142, 144-156 and 158-167 as depending directly or indirectly from one of claims 125, 143 and 157.

It is believed that the above represents a complete response to the outstanding Office action. Reconsideration and early allowance are respectfully requested.

Respectfully submitted,

By Stephen S. Wentsler  
Stephen S. Wentsler  
Registration No. 46,403  
Attorney for Applicants  
DINSMORE & SHOHL LLP  
1900 Chemed Center  
255 East Fifth Street  
Cincinnati, Ohio 45202  
(513) 977-8683

986845